

**REMARKS**

Reconsideration is requested.

Claims 1-7 and 9-14 have been canceled, without prejudice. Claims 8 and 15-24 are pending. New claims 18-24 have been added to define further aspects of the disclosed invention. Support for the amended claims can be found throughout the specification. No new matter has been added.

Claim 8 has been revised to obviate the objection stated on page 2 of the Office Action. The Examiner's helpful suggestions have been adopted in the above amendments. Withdrawal of the objections to claim 8 is requested.

The Section 112, second paragraph, rejection of claim 17 is obviated by the above amendments. Withdrawal of the rejection is requested.

The Section 103 rejection of claims 8 and 15-17 over Van Bossuyt (U.S. Patent No. 5,866,167) in view of Rolf (U.S. Patent No. 5,804,213), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Van Bossuyt is understood to describe a pharmaceutical composition comprising a non-viable lysate (keratinocyte in lyophilized form, column 10 line 42).

Van Bossuyt does not teach or suggest however the inclusion of the antiflocculant and/ or antisedimentation agent Xanthan gum of the present claims.

The objective problem to be solved is complex formation and flocculation resulting from the lysis of cells, which releases many components in various forms, forming an extremely complex mixture of constituents such as proteins, glycoproteins, polysaccharides, lipids, nucleic acids etc. All these components may interact with each

other, significantly increasing the possibility for complex formation and flocculation, ultimately resulting in a non-stable solution or suspension and sedimentation of part of these components.

The objective problem is solved in the present invention by addition of antiflocculant and/ or antisedimentation agent Xanthan gum.

The identification and inclusion of Xanthan gum in the presently claimed composition and method as an antiflocculant/antisedimentation agent to prevent flocculation or sedimentation was not obvious.

Specifically, the behavioral interactions between the compounds leading to flocculation and subsequent sedimentation are generally unpredictable. Similarly, the manner by which potential antiflocculants interact with the compounds of the lysate are also unpredictable and prevention of these undesirable physical processes can not be achieved by simply adding a viscosity-increasing agent.

Van Bossuyt does not teach or suggest the use of any antiflocculant/antisedimentation agents. For a person of ordinary skill in the art faced with the problem of flocculation and antisedimentation looking to the composition described in Van Bossuyt was not provided with a solution.

The Examiner's secondary reference, Rolf, fails to cure the deficiencies of the primary reference. The secondary reference is understood to describe use of xanthan gum as a gelling agent. Rolf is understood to relate to a wound dressing containing hydrocolloids as gelling agent.

It would not have been obvious to have combined Van Bossuyt and Rolf to have made the presently claimed invention.

Rolf provides preferred hydrocolloids apart from xanthan gum, such as Guar gum and Locust bean gum. Moreover, the Examiner is urged to appreciate that all the hydrocolloids of Rolf induce flocculation and are well-known flocculants. This concept has been well established and known in the art. See attached copy of Hodge et al.

The presently claimed invention is the result of extensive research which involved discovery of useful antiflocculant/antisedimentation agents.

The person of ordinary skill in the art would not have expected xanthan gum to inhibit flocculation, since it was well known that xanthan gum actually induces flocculation in many pharmaceutical and food formulations. See attached abstracts. The fact that xanthan gum, alone or in combination with maltodextrin, inhibited flocculation and sedimentation in the cell lysates of the present invention is therefore to be considered a surprising and unexpected finding, and using this agent for that purpose is certainly not obvious.

A person ordinarily skilled in the art confronted with problem of complex formation and flocculation resulting from the lysis of keratinocyte cells as obtained from the teaching of Van Bossuyt and being aware of common knowledge (as described in the attached) that hydrocolloids specifically guar gum, locust bean gum and xanthan gum are well-known flocculants would not have been motivated to refer to nor to combine the teachings of Rolf to solve the technical problem of the present invention.

The presently claimed invention is submitted to be patentable over the cited art and withdrawal of the Section 103 rejection is requested.

VERVAET et al.  
Appl. No. 10/537,301  
July 25, 2006

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned in the event anything further is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



B.J. Sadoff  
Reg. No. 36,663

BJS:  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100